OFFICE OF SPECIAL MASTERS

(Filed: September 3, 2004)
(REISSUED FOR PUBLICATION: FEBRUARY 1, 2005)

ELIZABETH O. SCHNEIDER,)	
as natural mother and guardian of her son,)	
JOHN R. SCHNEIDER,)	
)	
Petitioner,)	
)	
v.)	No. 99-0160V
)	PUBLISH
SECRETARY OF)	
HEALTH AND HUMAN SERVICES,)	
)	
Respondent.)	
)	

DECISION

Petitioner, Elizabeth O. Schneider (Ms. Schneider), as guardian of her son, John R. Schneider (John), seeks compensation under the National Vaccine Injury Compensation Program (Program). John suffers a constellation of very serious neurological symptoms. Although John's voluminous medical records indicate that none of John's numerous treating physicians from a variety of exceptional medical institutions has determined ever a definitive cause for John's devastating condition, Ms. Schneider implicates the first in a series of three Hepatitis B vaccinations that John received on September 25, 1993, when he was a neonate.

The special master convened a hearing in Cleveland, Ohio, on July 20, 2004. Appearing *pro se*, Ms. Schneider offered a statement of facts and a summary of her medical contentions.² John A.

¹ The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

² Antonios P. Tsarouhas, Esq. (Mr. Tsarouhas), represented initially Ms. Schneider. Ms. Schneider "fired" Mr. Tsarouhas in May 2003. Petitioner's Filing, filed January 21, 2004, Exhibit 3 at 1.

Tilelli, M.D. (Dr. Tilelli), testified as Ms. Schneider's medical expert.³ Mary Anne Guggenheim, M.D. (Dr. Guggenheim), testified as respondent's medical expert.⁴

THE STATUTORY SCHEME

Ms. Schneider pursues entitlement to a Program award using two distinct legal standards. First, Ms. Schneider presents a case under the legal standard, referred to commonly as a Table claim, that confers a presumption of causation in certain circumstances. See § 300aa-11(c)(1)(A)-(C)(i); § 300aa-13(a)(1)(A). In particular, Ms. Schneider asserts that following the administration of a vaccine--Hepatitis B--included in the Vaccine Injury Table (Table), 42 C.F.R. §100.3(a)(VIII), John sustained the first symptom or manifestation of onset of an injury--anaphylaxis or anaphylactic shock--listed in the Table for Hepatitis B, 42 C.F.R. § 100.3(a)(VIII)(A), within the period--4 hours-provided by the Table for Hepatitis B, id., and that his condition represents the acute complication, sequela or pathological consequence of the anaphylaxis or anaphylactic shock. 42 C.F.R. § 100.3(a)(VIII)(B). The qualifications and aids to interpretation (QAI) that apply to the Table define anaphylaxis or anaphylactic shock as "an acute, severe, and potentially lethal systemic allergic reaction." 42 C.F.R. § 100.3(b)(1). Manifestations of anaphylaxis or anaphylactic shock may include "[c]yanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea." Id. Second, Ms. Schneider presents a case under the legal standard based upon traditional tort principles governing actual causation. In particular, Ms. Schneider asserts that "but for" the administration of John's September 25, 1993 Hepatitis B vaccination, John would not have been injured, and that John's September 25, 1993 Hepatitis B vaccination was a "substantial factor in bringing about" John's injury. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Ms. Schneider must demonstrate a case under either legal standard "by a preponderance of the evidence." § 300aa-13(a)(1)(A). The preponderance of the evidence rule requires the special master to believe that the existence of a fact is more likely than not. See, e.g., Thornton v. Secretary of HHS, 35 Fed. Cl. 432, 440 (1996); see also In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring), quoting F. James, Civil Procedure 250-51 (1965). Mere conjecture or speculation will not meet the preponderance of the evidence rule. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984); Centmehaiev v. Secretary of HHS, 32 Fed. Cl. 612 (1995), aff'd, 73 F.3d 381 (Fed. Cir. 1995).

³ Dr. Tilelli is board-certified in pediatrics, in pediatric critical care, in emergency medicine and in medical toxicology. Notice of Filing Expert Curriculum Vitae (Dr. Tilelli's CV), filed August 13, 1999, at 2.

⁴ Dr. Guggenheim is board-certified in pediatrics and in neurology, with a special competence in child neurology. Respondent's exhibit (R. ex.) B at 2.

DISCUSSION

Ms. Schneider's Table Claim

While the Table relaxes a petitioner's "proof of causation for injuries satisfying the Table," Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992), a petitioner's Table claim may present nonetheless subtly complex factual, medical and legal issues. For instance, as the United States Court of Federal Claims counseled in Abbott v. Secretary of HHS, 27 Fed. Cl. 792 (1993), "Congress intended [the Act] to be understood--and to be applied--as it would be by a medical professional." *Id.* at 794. Thus, Congress prohibited special masters from awarding compensation "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a). Numerous cases construe § 300aa-13(a). The cases hold uniformly that if an injured person's medical records do not disclose a *diagnosis* that the injured person's symptoms constitute a Table injury, then the petitioner must submit a medical expert's opinion interpreting the injured person's symptoms as a Table injury. See, e.g., Shaw v. Secretary of HHS, 18 Cl. Ct. 646, 650 (1989); Bernard v. Secretary of HHS, No. 91-1301V, 1992 WL 101097, *1 (Cl. Ct. Spec. Mstr. Apr. 24, 1992); Dickerson v. Secretary of HHS, 35 Fed. Cl. 593, 599 (1996). The cases reason that "special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone." Raley v. Secretary of HHS, No. 91-0732V, 1998 WL 681467, *9 (Fed. Cl. Spec. Mstr. Aug. 31, 1998).

Ms. Schneider acknowledges that John's medical records that are contemporaneous with John's September 25, 1993 Hepatitis B vaccination do not reflect that any medical personnel rendered a diagnosis that John experienced the onset of anaphylaxis or anaphylactic shock within four hours after his September 25, 1993 Hepatitis B vaccination. *See* Transcript (Tr.), filed August 25, 2004, at 4-5. Nevertheless, Ms. Schneider insists that John's medical records that are contemporaneous with John's September 25, 1993 Hepatitis B vaccination reveal "an event" that is consistent with anaphylaxis or anaphylactic shock. Tr. at 5-6, 24-25, 27. Ms. Schneider grounds her argument upon assumptions of fact that she developed from her lay interpretation of John's medical records. According to Ms. Schneider, John received his Hepatitis B vaccination at 8:58 a.m., on September 25, 1993, and John exhibited an "ectopic" heart beat by 9:15 a.m., on September 25, 1993. *See* Addition to Petition (Supp. Pet.), filed October 6, 2003, at 1; *see also* Petitioner's Statement (Statement), filed July 20, 2004, at 1; Tr. at 58, 122.

At hearing, Dr. Guggenheim refuted persuasively one of Ms. Schneider's central assumptions of fact. While Dr. Guggenheim agreed that John exhibited an "ectopic" heart beat at 9:15 a.m., on September 25, 1993, see Tr. at 88-89, 107, citing Petitioner's exhibit (Pet. ex.) 4 at 15, Dr. Guggenheim stated that John's medical records confirm that John received his Hepatitis B vaccination at 10:15 a.m., on September 25, 1993. See Tr. at 89, citing Pet. ex. 4 at 20. Thus, Dr. Guggenheim maintained that John's irregular heart beat--a symptom that Ms. Schneider identifies as proof of anaphylaxis or anaphylactic shock--preceded the administration of John's Hepatitis B vaccination. Tr. at 87, 89, 105, 107. Dr. Guggenheim explained clearly the fallacy of Ms. Schneider's lay interpretation of John's medical records: Ms. Schneider mistook simply the time

that a nurse acknowledged a physician's direction that a Hepatitis B vaccination be administered for the time that a nurse administered actually the Hepatitis B vaccination. *See* Tr. at 105-109, *comparing* Pet. ex. 4 at 7 with Pet. ex. 4 at 20. Dr. Tilelli concurred completely with Dr. Guggenheim's assessment of John's medical records. *See* Tr. at 116-17.

Regardless, Dr. Tilelli opined forcefully that John did not experience the onset of anaphylaxis or anaphylactic shock within four hours after his September 25, 1993 Hepatitis B vaccination. Tr. at 53-54, 59, 61, 63, 66-67, 73. Dr. Tilelli depicted anaphylaxis or anaphylactic shock as "a dramatic state associated with cardiovascular collapse attendant to immediate hypersensitivity." Tr. at 53-54; see also Tr. at 55, 73. Dr. Tilelli disputed emphatically that John's irregular heart beat on September 25, 1993, qualified as a symptom of anaphylaxis or anaphylactic shock. Tr. at 51, 54, 57-59, 66-67, 70, 73. Moreover, Dr. Tilelli stated that anaphylaxis or anaphylactic shock "requires two entities to be present that can't be present in a newborn:" a "prior exposure to the allergen" and "IGE, which newborns can't make." Tr. at 54; see also Tr. at 59, 70, 73, 75. Indeed, Dr. Tilelli offered that had John experienced anaphylaxis or anaphylactic shock after his first Hepatitis B vaccination as Ms. Schneider asserts, then John "should have" experienced also anaphylaxis or anaphylactic shock after "the second and third administrations of the [Hepatitis B] vaccine." Tr. at 54; see also Tr. at 60. Dr. Guggenheim concurred completely with Dr. Tilelli's opinion. See Tr. at 85-86, 90.

John's medical records that are contemporaneous with John's September 25, 1993 Hepatitis B vaccination do not substantiate that any of John's medical providers concluded that any symptoms that John may have exhibited within four hours after his September 25, 1993 Hepatitis B vaccination constitute the manifestation of anaphylaxis or anaphylactic shock. In addition, Ms. Schneider has not proffered a medical expert's opinion substantiating that any symptoms that John may have exhibited within four hours after his September 25, 1993 Hepatitis B vaccination constitute the manifestation of anaphylaxis or anaphylactic shock. Therefore, Ms. Schneider has not met the statutory requirements of a Table case. § 300aa-11(c); § 300aa-13(a).

Ms. Schneider's Actual Causation Claim

The Act "does not relax proof of causation in fact for non-Table injuries." *Grant*, 956 F.2d at 1148. Indeed, the United States Court of Appeals for the Federal Circuit has described Ms. Schneider's burden under the actual causation standard as "heavy." *Whitecotton v. Secretary of HHS*, 81 F.3d 1099, 1102 (Fed. Cir. 1996). The mere temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove actual causation. *See Grant*, 956 F.2d at 1148; *Wagner v. Secretary of HHS*, No. 90-1109V, 1992 WL 144668 (Cl. Ct. Spec. Mstr. June 8, 1992). Rather, Ms. Schneider must present "a medical theory," supported by "[a] reliable medical or scientific explanation," establishing "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Grant*, 956 F.2d at 1148; *see also Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994)(citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993)). "The analysis undergirding" the medical or scientific explanation must "fall within the range of accepted standards governing" medical or

scientific research. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995). Ms. Schneider's medical or scientific explanation need not be "medically or scientifically certain." *Knudsen*, 35 F.3d at 549. But, Ms. Schneider's medical or scientific explanation must be "logical" and "probable," given "the circumstances of the particular case." *Knudsen*, 35 F.3d at 548-49.

Ms. Schneider advances two actual causation theories. At the outset, Ms. Schneider contends that John suffered a "demyelinating encephalopathy" that is related to his September 25, 1993 Hepatitis B vaccination. Tr. at 49-50; *see also* Tr. at 57-58, 61, 65-66, 69; Notice of Filing Expert Report (Dr. Tilelli's Opinion), filed June 30, 1999, at 3. Next, Ms. Schneider contends that John suffered "chemical poisoning" from his September 25, 1993 Hepatitis B vaccination. Statement at 2; *see also* Tr. at 31-33. Ms. Schneider identifies the "agent" as "phenylmethylsulphonyl flouride," or "PMSF." Statement at 2; *see also* Tr. at 38-40, 42-43.

Dr. Tilelli characterized John's condition as a "demyelinating encephalopathy." Tr. at 49-50; *see also* Tr. at 57-58, 61, 65-66, 69-70; Dr. Tilelli's Opinion at 3. Dr. Tilelli grounded apparently his characterization of John's condition upon a "sural nerve biopsy" showing "demyelination" and upon early magnetic resonance imaging (MRI) "findings" suggesting "white matter disease." Dr. Tilelli's Opinion at 2; *see also* Tr. at 58, 66, 117-18. In Dr. Tilelli's view, John was "a normal baby" at birth who developed "neurologic symptoms" in January 1994. Tr. at 56-57; *see also* Tr. at 49-52, 64, 119. According to Dr. Tilelli, the temporal relationship between the administration of John's September 25, 1993 Hepatitis B vaccination and the manifestations of John's neurological condition in January 1994 is consistent with an immune process leading to central nervous system damage. Tr. at 69; *see also* Tr. at 49-50, 66. Therefore, Dr. Tilelli offered that John's September 25, 1993 Hepatitis B vaccination caused John's neurological condition. Tr. at 49-50.⁵

Dr. Guggenheim disputed that John exhibits a demyelinating encephalopathy. Tr. at 90-93, 98, 101, 110, 115. Dr. Guggenheim asserted that John's MRI scans reflected "normal maturation of myelin" in John's "central nervous system." Tr. at 90; *see also* Tr. at 91-93, 101, 115. In

⁵ The hearing record is somewhat confusing. Based upon additional factual information that Ms. Schneider provided to him after he prepared his original report in 1999, and based upon his understanding of Dr. Guggenheim's opinion, Dr. Tilelli indicated that John may have exhibited neurological symptoms during the neonatal period, coincident with his September 25, 1999 Hepatitis B vaccination. *See* Tr. at 51-52, 55-58, 64, 66-70. Therefore, during cross-examination and during examination by the special master, Dr. Tilelli retracted his original report, stating that he could not support a causal relationship between John's September 25, 1993 Hepatitis B vaccination and John's condition if the onset of John's condition occurred on September 25, 1993. *See* Tr. at 65-67. However, during examination by the special master, Dr. Guggenheim said that John did not exhibit manifestations of his neurological condition until January 1994. *See* Tr. at 112, 115. Thus, Dr. Guggenheim concurred with Dr. Tilelli about the timing of onset of John's neurological symptoms. *See* Tr. at 112, 115. During reexamination by the special master, Dr. Tilelli withdrew at least in part his retraction of his original report. Tr. at 118-19.

addition, Dr. Guggenheim asserted that demyelinating encephalopathies do not involve usually "seizures" or "epilepsy," a "major" component of John's condition. Tr. at 115. Moreover, Dr. Guggenheim asserted that Dr. Tilelli's reference to John's sural nerve biopsy result as evidence of a demyelinating central nervous system disorder is misguided. *See* Tr. at 96-99. Dr. Guggenheim explained that myelin coating peripheral nerves, such as the sural nerve, is "chemically different from the myelin that is present in the brain." Tr. at 96-97.

Dr. Tilelli acknowledged candidly that he does not possess adequate expertise to interpret MRI reports. Tr. at 118; *see also* Tr. at 63. Thus, Dr. Tilelli conceded readily that he must defer to Dr. Guggenheim's opinion that John does not suffer a demyelinating encephalopathy. *See* Tr. at 63, 65-66, 117-19. As a result, the special master accords naturally very little evidentiary weight to Dr. Tilelli's opinion that John's September 25, 1993 Hepatitis B vaccination caused John's condition. Therefore, the special master rejects Ms. Schneider's first actual causation theory.

Although Dr. Tilelli is a toxicologist, Dr. Tilelli professed ignorance regarding PMSF. Tr. at 53, 60. Therefore, Dr. Tilelli declined to offer an opinion about the "significance" of PMSF. Tr. at 60. Ms. Schneider has not been successful otherwise in retaining a qualified medical expert who is willing to review her Program case. *See* Tr. at 33-34; *see also* Petitioner's Filing, filed January 21, 2004, Exhibits 3-4. Thus, Ms. Schneider's second actual causation theory rests solely--and impermissibly--upon Ms. Schneider's unsubstantiated lay belief that John's Hepatitis B vaccination contained a toxin that injured John. *See* § 300aa-13(a). Therefore, the special master rejects Ms. Schneider's second actual causation theory.

The special master has canvassed the record as a whole. The special master has considered carefully Dr. Tilelli's testimony and Dr. Guggenheim's testimony. The special master determines that Ms. Schneider has not established under either of her actual causation theories that John's September 25, 1993 Hepatitis B vaccination caused actually John's condition.

At hearing, Ms. Schneider requested essentially that the special master compel the release of vaccine manufacturers' "confidential documents in full," as well as the testing of "all" Hepatitis B vaccine lots for the presence of PMSF. Tr. at 32-33. The special master denies Ms. Schneider's request as far beyond the scope of his authority. The special master recognizes certainly his role as "an inquisitor" in Program cases. *Munn v. Secretary of HHS*, 21 Cl.Ct. 345, 349 (1990). However, legislative history suggests fairly that the special master's investigative power is limited to "factual elements" of a petitioner's claim. H.R.REP. No. 99-908, pt. 1, at 17 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6344, 6357-58. Thus, in the special master's view, the Program is not the appropriate forum for--and a special master should not preside over wide-ranging discovery, or should not devise unique procedures, aimed at--developing original scientific or medical theses.⁶

⁶ Congress restricted sharply discovery, *see* § 300aa-12(d)(2)(E), placing the emphasis on the production of information that will assist the special master in evaluating a claim rather than on the production of just any potentially sensitive information that a petitioner desires in an attempt to (continued...)

Indeed, scientific or medical "research" conceived and conducted in the context of litigation poses an inherent danger: scientific or medical "research" conceived and conducted in the context of litigation is not subjected usually to the time-honored practices in the scientific and medical communities of peer-review and of publication--two of several, significant touchstones of evidentiary reliability. *See, e.g., Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593; 113 S.Ct. 2786, 2797 (1993)("[S]ubmission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected."); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995).

Precedent and the Act support wholly the special master's conservative--if not, extremely narrow--construction of a special master's function. In *Knudsen*, the Federal Circuit announced that "research" regarding "how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others" is properly "for scientists, engineers, and doctors working" outside the judicial arena "in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies," and not for the Court of Federal Claims. Knudsen, 35 F.3d at 549. Instead, the Federal Circuit proclaimed that special masters determine merely "based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the child's injury. . . , and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury." Id., citing 42 U.S.C. § 300aa-13(a)(1), (b)(1). Moreover, the Program is just one component of an intricate statutory structure establishing the Nation's policy on childhood vaccines. In the intricate statutory structure, Congress directed the formation of a National Vaccine Program in the Department of Health and Human Services, see § 300aa-1 & 2; the formation of the National Vaccine Advisory Committee, see § 300aa-5; and the formation of the Advisory Commission on Childhood Vaccines. See § 300aa-19. The Director of the National Vaccine Program is responsible for "coordinat[ing] and provid[ing] direction for research . . . to prevent adverse reactions to vaccines." § 300aa-2(a)(1). The National Vaccine Advisory Committee, comprised of "individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations," supports the Director of the National Vaccine Program by "recommend[ing] research priorities and other measures the

⁶(...continued)

establish a basis for a claim. See e.g., § 300aa-12(d)(3)(B); see also H.R.REP. No. 99-908, pt. 1, at 16 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6344, 6357 ("Because the only issues relevant to the compensation proceeding are whether the petitioner suffered a compensable injury, and, if so, the extent of compensable damages, there should be no need for a wider inquiry, which might be appropriate in a civil action raising other issues."); In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or Similar Neurodevelopmental Disorder, Autism Master File, Ruling Concerning Motion for Discovery From Merck Re MMR Vaccine (Fed. Cl. Spec. Mstr. July 16, 2004).

Director of the Program should take to enhance the safety and efficacy of vaccines." § 300aa-5(b)(2). The Advisory Commission on Childhood Vaccines, comprised of health professionals, legal representatives of vaccine-injured children, attorneys, and government officials, performs duties that are similar to the National Vaccine Advisory Committee. *See* § 300aa-19(f). In addition, in the intricate statutory structure, Congress directed the Secretary of the Department of Health and Human Services to contract with the Institute of Medicine (IOM)--the august division of the National Academy of Sciences (NAS) chartered in 1970--or with "other appropriate nonprofit private groups or associations" to canvass scientific and medical evidence regarding adverse consequences of routine childhood vaccines. National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-660, §§ 312-13, 100 Stat. 3779-82 (1986). Thus, in the intricate statutory structure, Congress has provided both a mechanism distinct from the Program to foster fitting scientific or medical research regarding vaccine safety and a mechanism distinct from the Program to foster fitting review of scientific or medical research regarding vaccine safety accine safety.

CONCLUSION

The special master is exceedingly sympathetic about Ms. Schneider's and John's circumstances. However, the special master is constrained to hold that Ms. Schneider is not entitled to Program compensation. Therefore, in the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

⁷ The IOM publishes conclusions from its reviews. *See e.g.*, Christopher P. Howson, *et al.*, Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines (National Academy Press 1991); Kathleen R. Stratton, *et al.*, Institute of Medicine, DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis (National Academy Press 1994); Kathleen R. Stratton, *et al.*, Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality (National Academy Press 1994). Special masters consider generally the IOM's conclusions to be authoritative. *See, e.g., Terran v. Secretary of HHS*, No. 95-0451V, 1998 WL 55290, *10 (Fed. Cl. Spec. Mstr. Jan. 23, 1998); *Raj v. Secretary of HHS*, No. 96-0294V, 2001 WL 963984, *8 n.15 (Fed. Cl. Spec. Mstr. July 31, 2001) citing *Asche-Robinson v. Secretary of HHS*, No. 94-1096V, 1998 WL 994191, *7-8 (Fed. Cl. Spec. Mstr. Dec. 22, 1998).

The clerk of court shall send Ms. Schneider's copy overnight express delivery.	y of this decision to Ms. Schneider by
	John F. Edwards Special Master